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EXAMINER	
LAVERT, NICOLE F	

ART UNIT	PAPER NUMBER
3762	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/734,088	SUNDBERG, GREGORY L.	
	Examiner	Art Unit	
	NICOLE F. LAVERT	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-7,21-26 and 43-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-7,21-26 and 43-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 October 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/31/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 1-3, 5-7, 23-24, 43-47, 51 & 55-60** rejected under 35 U.S.C. 102(b) as being anticipated by Cross et al. (US 5,935,159).

For **claim 1**, Cross et al. discloses, an implantable lead comprising [(col 1, ln 8-10) & (Fig 1, 10)]: a tubular lead body including an inner body surface with material defining an interior lumen extending through the tubular lead body such that the inner body surface and the material defining the interior lumen define a hollow between the inner body surface and the material defining the interior lumen (Fig 2, 10 & 100); at least one electrode disposed along the tubular lead body (Fig 1, 18 & 20); at least one conductor electrically coupled with the at least one electrode and disposed in the hollow (Fig 3, 104-110), and at least one filler disposed within the hollow such that the hollow is substantially filled (Fig 2 & 3, 102 & 190-196), the filler defining a plurality of recesses along a portion extending along the material defining the interior lumen (col 2, ln 1-9 & 33-66). Note that the disclosed elongated lead body contains an outer insulative tube that defines an inner, cylindrically shape in which the disclosed core member extends through, providing the claimed inner body surface and material defining an interior lumen. The Examiner is interpreting the disclose core member within the outer insulative tube as the claimed inner body surface defining a hollow which a filler is disposed within (Fig 3, 100 &

102). Also note, the Examiner is interpreting the disclosed grooves of the core as being the claimed recesses (Fig 2, 102 & 190-196).

In regards to **claim 2**, Cross et al. discloses, the implantable lead as recited in claim 1 (Fig 1, 10), wherein the plurality of recesses comprise include non occupied recesses, the non occupied recesses providing compression features [(col 2, ln 33-51) & (Fig 2, 102, 190-196 & 180-186)]. Note that the disclosed radially extending portions perform the same tasks as the claimed compression features (Fig 2, 180-186).

In regards to **claim 3**, Cross et al. discloses, the implantable lead as recited in claim 2 (Fig 1, 10), wherein the compression features include compression waves disposed on the inner perimeter of the one or more fillers [(col 2, ln 33-51) & (Fig 2, 102 & 180-186)].

In regards to **claim 5**, Cross et al. discloses, the implantable lead as recited in claim 1 (Fig 1, 10), further comprising a coiled conductor forming a lumen therein, the coiled conductor disposed within the lead body, and a coil conductor longitudinal axis is offset from a lead body longitudinal axis [(col 2, ln 52-66) & (Fig 3, 104-110)].

In regards to **claim 6**, Cross et al. discloses, the implantable lead as recited in claim 1 (Fig 1, 10), wherein the one-or at least one filler is generally C-shaped (Fig 2, 102).

In regards to **claim 7**, Cross et al. discloses, the implantable lead as recited in claim 1 (Fig 1, 10), wherein the at least one filler is formed of silicone [(col 3, ln 10-24) & (Fig 2, 102)].

In regards to **claim 23**, Cross et al. discloses, the implantable lead as recited in claim 1 (Fig 1, 10), wherein at least a first and a second insulated cable conductor are disposed in the hollow distally between the first and second filler end [(col 2, ln 33-66) & (Fig 3, 104-110)].

In regards to **claim 24**, Cross et al. discloses, the implantable lead as recited in claim 1 (Fig 1, 10), further comprising an active fixation assembly disposed at a distal end of the tubular lead body [(col 2, ln 3-6) & (Fig 1, 14)].

In regards to **claim 43**, Cross et al. discloses, the implantable lead as recited in claim 1 (Fig 1, 10), wherein the hollow comprises an tubular isolated lumen (col 2,ln 33-66).

For **claim 44**, Cross et al. discloses, an apparatus, comprising: a lead body defining a lead lumen [(col 1, ln 8-10) & (Fig 1, 10)]; an electrode coupled to the lead body (Fig 1, 18 & 20); a coiled conductor electrically coupled to the electrode and extending through the lead lumen (Fig 3, 104-110); and a filler disposed in the lead lumen partially around the coiled conductor, the filler defining a plurality of recesses disposed along a portion of the filler adjacent the coiled conductor (Fig 2 & 3, 102, 190-196 & 104-110).

In regards to **claim 45**, Cross et al. discloses, the apparatus of claim 44 (Fig 1, 10), wherein the filler includes silicone [(col 3, ln 10-24) & (Fig 2, 102)].

In regards to **claim 46**, Cross et al. discloses, the apparatus of claim 44 (Fig 1, 10), wherein the filler comprises a C-shape (Fig 2, 102).

In regards to **claim 47**, Cross et al. discloses, the apparatus of claim 44 (Fig 1, 10), wherein the lead body is biocompatible [(col 3, ln 10-24) & (Fig 3, 100)]. Note that the disclosed materials of the outer tube, such as silicone rubber, is an example of a biocompatible material therefore providing the claimed biocompatible lead body (col 3, ln 10-24).

For **claim 51**, Cross et al. discloses, an apparatus, comprising: a lead body defining a lead lumen [(col 1, ln 8-10) & (Fig 1, 10)]; an electrode coupled to the lead body (Fig 1, 18 & 20); a conductor electrically coupled to the electrode and extending through the lead lumen (Fig 3, 104-

110); and material defining an interior lumen extending through the lead lumen positioned by a filler disposed in the lead lumen with the filler defining recesses disposed along a portion of the filler adjacent the material defining the interior lumen, with the conductor disposed outside the material defining the interior lumen and the recesses [(col 2, ln 1-9 & 33-66) & (Fig 2 & 3, 102, 190-196 & 104-110)].

In regards to **claim 55**, Cross et al. discloses, the apparatus of claim 51 (Fig 1, 10), wherein the material defining the interior lumen comprises a coil [(col 2, ln 33-66) & (Fig 3, 104-110)].

In regards to **claim 56**, Cross et al. discloses, the apparatus of claim 55 (Fig 1, 10), wherein the coil is conductive [(col 2, ln 33-66) & (Fig 3, 104-110)].

In regards to **claim 57**, Cross et al. discloses, the apparatus of claim 56 (Fig 1, 10), wherein the coil is electrically insulated by coil insulator [(col 2, ln 33-66)-(col 3, ln 1-9) & (Fig 3, 104-110 & 112-118)]. Note the Examiner is interpreting the disclosed outer insulative sheath surrounding the conductors as performing the same task as the claimed electrically insulated coil insulator (Fig 3, 112-118).

In regards to **claim 58**, Cross et al. discloses, the apparatus of claim 56 (Fig 1, 10), wherein the conductor is electrically insulated by conductor insulator (Fig 3, 104-110 & 112-118).

In regards to **claim 59**, Cross et al. discloses, the apparatus of claim 51 (Fig 1, 10), wherein the lead body is biocompatible [(col 3, ln 10-24) & (Fig 3, 100)]. Note that the disclosed materials of the outer tube, such as silicone rubber, is an example of a biocompatible material therefore providing the claimed biocompatible lead body (col 3, ln 10-24).

In regards to **claim 60**, Cross et al. discloses, the apparatus of claim 51 (Fig 1, 10), wherein the filler comprises a C-shape (Fig 2, 102).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. **Claim 21** is rejected under 35 U.S.C. 103(a) as being unpatentable over Cross et al. (US 5,935,159).

Cross et al. shows all features of the instantly claimed invention as discussed above.

Cross et al. fails to disclose an implantable medical lead comprised of a filler having a greater flexibility then the flexibility of a tubular lead body.

However, Cross et al. does teach an invention relating to medical electrical leads comprising an outer, insulative tube and core extended through the disclosed outer tube, in which the Examiner is interpreting the core member as the claimed filler. Cross et al. teaches that the core may be extruded from a different plastic than the outer tube, such as being fabricated of polyurethane [(col 2, ln 33-66), (col 3, ln 10-50) & (Fig 3, 100 & 102)]. Note that it would have been well known to one of ordinary skill in the art to use a highly, more flexible polyurethane plastic, such as ETFE or PTFE, in order to construct the greater flexible filler as instantly claimed (col 3, ln 10-24).

Therefore, it would have been obvious to one of ordinary skill at the time of the invention to have incorporated in Cross et al. a filler having a greater flexibility then the flexibility of a

tubular lead body as is instantly claimed in order to provide predictable results pertaining to providing desired mechanical characteristics of a lead body in regards to the migration of the conductors through insulation due to repeated flexing of the lead body (col 3, ln 10-50).

5. **Claim 25** is rejected under 35 U.S.C. 103(a) as being unpatentable over Cross et al. (US 5,935,159).

Cross et al. shows all features of the instantly claimed invention as discussed above.

Cross et al. fails to disclose an implantable medical lead comprised of at least one conductor which includes insulation of the group including PTFE, ETFE and polyurethane.

However, Cross et al. does teach an invention relating to medical leads comprising of multiple coiled conductors surrounded by an outer insulative sheath [(col 2, ln 33-66)-(col 3, ln 1-9) & (Fig 3, 104-110 & 112-118)]. Note that it is well known to those of ordinary skill in the art that the disclosed outer insulative sheath may be fabricated from insulated plastics such as the claimed materials.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have incorporated in Cross et al. the use of at least one conductor which includes insulation of the group including PTFE, ETFE and polyurethane as instantly claimed in order to provide predictable results pertaining to providing an overall diameter for the insulated conductors so that electrical stimulus which travels through the multiple conductors is effectively applied [(col 2, ln 33-66)-(col 3, ln 1-9) & (Fig 3, 104-110 & 112-118)].

6. **Claims 49-50 & 53-54** are rejected under 35 U.S.C. 103(a) as being unpatentable over Cross et al. (US 5,935,159).

Cross et al. shows all features of the instantly claimed invention as discussed above.

Cross et al. fails to disclose an implantable medical lead comprising a second filler disposed in a lead lumen wherein the second filler defines a plurality of recesses disposed along a portion of the second filler adjacent a coiled conductor.

However, Cross et al. does teach an invention relating to medical leads further including a lead comprising an outer insulative tube body with a core member consisting of four radially extending portions disposed within the disclosed outer insulative tube, in which the core member has multiple grooves that the conductors lay within (Fig 2 & 3, 100, 102, 180-186, 190-196 & 104-110). Note that the Examiner is interpreting the disclosed core member and grooves as performing the same task as the filler defining a plurality of recesses disposed within as instantly claimed (Fig 2, 102). Note that it is well known to those of ordinary skill in the art to consider to divide the disclosed extending portions into two groups to form two separate core members disposed adjacent to one another, (i.e. Fig 2, 186/184 & 180/182) therefore providing a first and second filler as is instantly claimed (Fig 2, 102 & 180-186).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have incorporated in Cross et al. the use of a second filler disposed in a lead lumen wherein the second filler defines a plurality of recesses disposed along a portion of the second filler adjacent a coiled conductor as is instantly claimed in order to provide predictable results pertaining to multiple circular cross-sections in which allows for insulated conductors having an outer diameter corresponding to the maximum width of the grooves (i.e. recesses) to be snapped into the grooves (col 2, ln 33-51).

7. **Claims 26 & 48** are rejected under 35 U.S.C. 103(a) as being unpatentable over Cross et al. (US 5,935,159) in view of Dahl et al. (5,366,496)

Cross et al. shows all features of the instantly claimed invention as discussed above.

Cross et al. fails to disclose an implantable medical lead comprising at least one coil conductor with an outer insulation surface contacting an outer insulation surface of a cabled conductor in which the cable conductor is disposed around the coiled conductor.

Dahl et al. teaches a body implantable tissue stimulation device including an elongate, flexible electrically conductive lead further comprising a shunt cable conductor with a dielectric sheath surrounding a conductive core in which also includes a dielectric coating [(col 2, ln 43-49), (col 8, ln 18-27), (col 9, 36-51-64) & (Fig 6, 194, 200, 198 & 196)]. Note that it is well known in the art that the disclosed conductive core may be in the form of a coiled conductor as is instantly claimed (Fig 6, 198).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Cross et al. with the use of the shunt cable conductor surrounding a conductive core as taught by Dahl et al. in order to provide predictable results pertaining to providing a highly conductive and fatigue-resisting conductor assembly in which provides parallel electrically conductive paths for increased electrode conductivity (Dahl, col 3, ln 29-32 & 51-64).

Response to Arguments

8. Applicant's arguments with respect to claims 1-3, 5-7, 21, 23-26 & 43-60 have been considered but are moot in view of the new ground(s) of rejection. See the above action

9. Applicant's arguments, filed 12 May 2008, with respect to the § 112 rejections have been fully considered and are persuasive. Therefore the above § 112 rejections have been withdrawn.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE F. LAVERT whose telephone number is (571)270-5040. The examiner can normally be reached on M-F 7:30-5:00p.m. (alt. fridays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762

/Nicole F. LaVert/
Examiner, Art Unit 3762